

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Serial No.: 10/804,576  
Confirmation No.: 7069  
Applicants: Frederick H. Miller  
Filed: March 19, 2004  
Art unit: 1615  
Examiner: Aradhana Sasan  
For: **MULTI-PHASE, MULTI-COMPARTMENT  
CAPSULAR DELIVERY APPARATUS AND  
METHODS FOR USING SAME**

Attorney Docket No.: 159.1001

MAIL STOP: AMENDMENT  
Commissioner for Patents  
Alexandria, VA 22313-1450

February 12, 2009

**INFORMATION DISCLOSURE**  
**STATEMENT UNDER 37 C.F.R. § 1.56**

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record documents listed on the accompanying Form PTO-1449 (1 page) for consideration by the Examiner in connection with the examination of the above-identified patent application.

In accordance with 37 C.F.R. 1.98(a)(2), a copy of each document cited in the FOREIGN PATENT DOCUMENTS and OTHER PRIOR ART sections of accompanying Form PTO-1449 must be provided and are enclosed herewith. If it is determined that a copy of any of the cited documents is missing and is required, the Examiner is respectfully requested to contact the undersigned so that the missing copy may be forwarded.

Applicant also respectfully advises the Examiner of the following related applications:

The instant application claims the benefit of:

U.S. Patent Application No. 10/368,951 filed February 18, 2003 (now abandoned); U.S. Patent Application No. 10/369,427 filed February 18, 2003 (now abandoned); U.S. Patent Application No. 10/369,244 filed February 18, 2003 (now abandoned); U.S. Patent Application No. 10/369,247 (now abandoned); and PCT Application No. US 2003/10816 filed on April 9, 2003, published as WO 2003/086267, (now expired).

Copending commonly assigned U.S. Patent Application No. 10/902,261, entitled "APPARATUS AND METHODS FOR DELIVERING A PLURALITY OF MEDICAMENTS FOR MANAGEMENT OF CO-MORBID DISEASES, ILLNESSES OR CONDITIONS". Applicants have also submitted a copy of the Office Action(s) issued in connection with the '261 application and any Response(s) thereto for the Examiner's review and consideration as (**Appendix A**). U.S. Patent Application No. 10/902,261 is a continuation-in-part of U.S. Patent Application No. 10/804,224 filed March 19, 2004 (now abandoned); which is a continuation-in-part of U.S. Patent Application No. 10/786,563 filed February 26, 2004 (now abandoned).

Copending commonly assigned U.S. Patent Application No. 10/902,270, entitled "APPARATUS AND METHODS FOR DELIVERING A PLURALITY OF MEDICAMENTS FOR MANAGEMENT OF A DISEASE ILLNESS OR CONDITION AFFECTING ONE OR MORE ORGAN SYSTEMS". Applicants have also submitted a copy of the Office Action(s) issued in connection with the '270 application and any Response(s) thereto for the Examiner's review and consideration as (**Appendix B**). U.S. Patent Application No. 10/902,270 is a continuation-in-part of U.S. Patent Application No. 10/804,225, filed March 19, 2004 (now abandoned), which is a continuation-in-part of 10/786,564 filed February 26, 2004, (now abandoned).

Applicants further hereby make of record documents listed as A05-A07 on the accompanying Form PTO-1449. Document A05 is a copy of an “Action for Declaratory Judgment and Breach of Contract” filed in the Circuit Court of the Thirteenth Judicial Circuit in and For Hillsborough County, Florida against Innercap Technologies, Inc., the assignee of the present application. The Examiner is specifically directed to page 7, paragraph 17., where plaintiff Nutrex Research Inc., stated that “*[Capsugel] is a division of [Pfizer] and utilizes a combination of technology developed by Capsugel and Pfizer, including Pfizer’s liquid encapsulation by microspray (“LEMS”) technology for capsule manufacturing. This technology is both different from the technology disclosed in Innercap’s patent applications, and was made public more than one year prior to the earliest priority date asserted for the remaining patent applications licensed to Nutrex under the License Agreement.*”

The Examiner is also directed to document A07 which is copy of “Inncap Technologies, Inc.’s Answer, Affirmative Defenses, and Counterclaims to Plaintiff Nutrex Research, Inc.’s Complaint”. Specifically, in the first full paragraph at page 7 of A07, Innercap denies that the technology used by Capsugel referenced in paragraph 17 of the Nutrex Complaint is different from the technology disclosed in Innercap’s patent applications. Innercap also stated that “*[it] is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies the same.*”

The Examiner’s attention is also directed to document A06 which is a copy of an “Action for Declaratory Judgment, Breach of Contract and Fraudulent or Negligent Inducement” filed in the Circuit Court of the Thirteenth Judicial Circuit in and For Hillsborough County, Florida against Innercap Technologies, Inc. Specifically, at page 5, paragraph 18, which repeats the statement made at paragraph 17 of A05. Also at page 10, paragraph 55 of A06, Nutrex stated that “*on further information and belief, Fred Miller [inventor of the instant application] and Innercap were aware that the subject matter claimed in the applications purportedly licensed to Nutrex was not patentable.*” Attachment 1 of A06 contains the referenced “Technology License Agreement.” Exhibit A to that License Agreement lists the instant application application, and the above-

mentioned copending commonly assigned U.S. patent application nos. 10/902,261 and 10/902,270.

The Examiner's attention is also directed to document A08. While this article published on January 2007, and therefore in and of itself does not qualify as prior art, it includes a discussion of differences between hard and soft gelatin capsules and filling hard gelatin capsules with a liquid. This document also contains a commentary on Capsugel technology.

It is respectfully requested that the documents cited on the accompanying Form PTO-1449 and Appendices be considered and made of record.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c), "before the mailing date of any final action under § 1.114," and is accompanied by an authorization to charge the undersigned Attorney Deposit Account No. 50-0552 the amount of \$180.00 for the fee set forth in § 1.17(p). If it is determined that any additional fee is due or an overpayment has been made in connection with the filing of this Information Disclosure Statement, the Examiner is authorized to charge said fee or to credit said overpayment to Attorney Deposit Account No. 50-0552.

Respectfully submitted,

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By: \_\_\_\_\_



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